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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Yang, et al.

Serial No.: 09/434,313

Filed: October 25, 1999

For: ETHYLENEDICYSTEINE (EC)-DRUG  
CONJUGATES, COMPOSITIONS AND  
METHODS FOR TISSUE SPECIFIC  
DISEASE IMAGING

Group Art Unit: 1619

Examiner: Jones, D.

Atty. Dkt. No.: UTXC:627

DECLARATION

We, David A. Yang, Chun-Wei Liu, Dongfang Yu and E. Edmond Kim, hereby declare as follows:

1. We are joint inventors of the subject matter disclosed and claimed in the referenced patent application.
2. We understand that the Patent and Trademark Examiner has found the claimed subject matter of the referenced application to be obviated by the publications of Ilgan *et al.* (*Cancer Biotherapy and Radiopharm.*, 13(6): 427-435, 1998), Yang *et al.* (*Pharm Res.*, 16(5): 743-750, 1999), and Zareneyrizi *et al.* (*Anti-Cancer Drugs*, 10: 685-692, 1999).

3. We are submitting this declaration to set forth evidence demonstrating that the authors of the foregoing articles that were not named as inventors did not, in fact, make an inventive contribution to the subject invention.

4. With respect to the Ilgan *et al.* article, the authors that were not named as inventors were Seyfettin Ilgan, Tetsuya Higuchi, Fereshteh Zareneyrizi, Hikmet Bayhan and Donald A. Podoloff. None of these individuals made an inventive contribution to the subject matter of the claims. Seyfettin Ilgan conducted animal imaging and autoradiographic studies. Tetsuya Higuchi conducted animal tissue distribution studies. Fereshteh Zareneyrizi assist animal preparation and animal imaging studies. Hikmet Bayhan assisted in interpreting animal test data. Donald A. Podoloff assisted in interpreting animal data prior to human use. Each of these individuals operated under the direction of one or more the inventors with respect to the studies that that individual carried out and did not contribute conceptually to the subject matter of the invention.

5. With respect to the Yang *et al.* article, the authors that were not named as inventors were Seyfettin Ilgan, Tetsuya Higuchi, Fereshteh Zareneyrizi, Chang-Sok Oh and Donald A. Podoloff. None of these individuals made an inventive contribution to the subject matter of the claims. Seyfettin Ilgan conducted animal imaging and autoradiographic studies. Tetsuya Higuchi conducted animal tissue distribution studies. Fereshteh Zareneyrizi assisted in animal preparation and animal imaging studies. Chang-Sok Oh carried out chemistry data analysis. Donald A. Podoloff assist interpretate animal data prior to human use. Each of these individuals operated under the direction of one or more the inventors with respect to the studies that that individual carried out and did not contribute conceptually to the subject matter of the invention.

6. With respect to the Zareneyrizi *et al.* article, the authors that were not named as inventors were Seyfettin Ilgan, Tetsuya Higuchi, Fereshteh Zareneyrizi, Wayne Tansey and Donald A. Podoloff. None of these individuals made an inventive contribution to the subject matter of the claims. Seyfettin Ilgan conducted animal imaging and autoradiograph studies. Tetsuya Higuchi conducted animal tissue distribution studies. Fereshteh Zareneyrizi assisted in animal preparation and animal imaging studies. Wayne Tansey carried out chromatographic analysis of labeled agents. Donald Podoloff assisted in the interpretation of animal data prior to human use. Each of these individuals operated under the direction of one or more the inventors with respect to the studies that that individual carried out and did not contribute conceptually to the subject matter of the invention.

7. We further understand that the Examiner has cited the article of Mang'era *et al.* (Jml. Labelled Cmpds and Radiopharm., 42:683-699, 1999) as relevant to patentability. While we disagree that Mang'era *et al.* is relevant to patentability for the reasons set forth in our response (incorporated herein by reference), we hereby bring to the Examiner's attention the fact that an example of our invention was made in this country prior to the publication of Mang'era *et al.* This is shown, for example, by the above article of Ilgan *et al.* which was published in December, 1998. The Ilgan *et al.* article, which emanated from our laboratory, demonstrates the preparation and testing of Tc-99m ethylenedicysteine(EC)-folate as a tumor imaging agent in this country prior to the effective publication date of the Mang'era *et al.* article.

8. We hereby declare that all statements made of our own knowledge are true and all statements made on information are believed to be true and further that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

imprisonment or both under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issued thereon.

Date: 10-2-01

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Date: 10-2-01

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